FOOD ADDITIVES UNDER THE FEDERAL LAW

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Ladies and Gentlemen, it is a real pleasure for me to attend your annual meeting and to discuss with you a few of the problems in which we have a mutual interest. This interest is both official and personal, since we are concerned not only with effectively fulfilling our obligations as regulatory officials in raising the standards of cleanliness and safety of our food supply but also in sharing as consumers in the rewards of an effective program in this field.

The title "Food Additives Under the Federal Law" encompasses a problem with many facets. Bacterial contamination of foods might properly be discussed under this broad heading. I have been informed, however, that many of you are particularly desirous of a brief review of the present situation under the Federal Food, Drug, and Cosmetic Act as it relates to chemical additives and vitamin fortification.

It is perhaps unfortunate that the term "chemical additive" may convey to a substantial number of people the meaning that the additive is in some way harmful or detrimental to the food. Such individuals fail to appreciate that foods themselves are chemicals or mixtures of chemicals and that chemical processes are frequently involved in the production and processing of foods both in the home and in commercial establishments. We receive many inquiries in which the misconception of the terms "chemical" and "chemistry" distort the real problem with which the inquirers are concerned, namely, the safety of our food supply.

Most of you are familiar with the provisions of the Federal law which are designed to safeguard the safety of our food supply. It does, however, seem desirable to review these provisions briefly at this time. The statute prohibits entirely the unnecessary addition of a poisonous or deleterious ingredient to a food. In recognition of the existence of naturally appearing constituents in foods which may be deemed to be poisonous or deleterious, the law provides that the test of legality shall be whether the quantity of the naturally appearing constituent is such as to render the article ordinarily injurious to health. Special consideration is likewise given to the addition of a poisonous or deleterious ingredient to a food in those instances in which its use is required in the production of the food or which cannot be avoided by good manufacturing practice. In the latter situation, the Act authorizes the Secretary of the Department of Health, Education, and Welfare to establish safe tolerance levels for the added poisonous or deleterious ingredients. In establishing such tolerances, the Secretary must take into account not only the extent to which the use of the substance may be required or cannot be avoided in production, but also other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

The intent of these various provisions of the Act to make our food supply safe is clear. The road to the objective is not always, however, a dual super highway,
and reaching the destination may be considerably delayed by unfinished parts of the highway occasioned by inadequate or poorly designed equipment or lack of manpower and funds to complete the job. It would be well, perhaps, at this point to repeat what the Commissioner and other spokesmen for the Food and Drug Administration have said on many occasions. We sincerely believe that our food supply is the safest and the cleanest available in the world. This situation could not exist were it not for the sincere desire on the part of the vast majority of food manufacturers to comply with the food laws controlling their businesses and the wholehearted cooperation which such manufacturers extend to food control officials.

But as with most phases of our life, the situation is not static, new products are developed, new uses for old products are found, and advances in food technology are constantly being sought. These bring with them new problems or revitalized old ones. Advances in methods of analyses and pharmacological evaluation of food ingredients make it necessary that we frequently reappraise our policies and procedures in this field. The continually growing demand for commercially prepared foods of all kinds for home use has stimulated food producers to seek newer and better ways of preserving the palatability and attractiveness of their products. This has brought about the use or proposed use of many new substances as antioxidants, stabilizers, plasticizers, preservatives, inhibitors, softeners, emulsifiers, all which perform some function not directly concerned with the nutritive properties of the food. Obviously, their physiological effect when ingested by man is a proper matter of concern both to the regulatory official and the food manufacturer. The conscientious manufacturer will make a careful study of the toxicological properties of his product, not only in the light of the prohibition of the law against the unnecessary addition of a poisonous or deleterious ingredient to a food, but because he wants his products to be safe. Generally, it is not difficult to establish the unsuitability of an ingredient because of its acute toxicity and this is but a minor part of the problem. The adulteration sections of the law have much greater meaning than merely prohibiting the acutely toxic substance. Since most of us consume at least some commercially prepared foods over most of our life span, the chronic effects of these additives must be carefully evaluated. We have frequently asked what studies should be made to establish the safety of a food ingredient. As with most problems of this kind there is no one answer to the question. The facts of a given case must be given careful consideration. We have, however, expressed the opinion that the minimum study of an additive should cover at least the following basic points:

1. Establishment of the chemical identity and analytical methods of detection, identification, and quantitative estimation of the proposed additive.

2. Investigations of acute toxicity in test animals which should not be limited to rodent species but should include also one or more non-rodent species.

3. Study of subacute and chronic toxicity effects including not only growth, mortality, and reproduction patterns, but also blood level studies, metabolic fate of the compound, examination of organs and tissues, and similar criteria.

It must be kept in mind that a proposed ingredient, if deemed acceptable as an additive to a particular food, may quickly be found to attribute desirable properties to other foods and thus the quantity to be ingested may be substantially increased over that to be anticipated from the original proposal.

In the case of foods generally, the Federal law places responsibility for using only suitable and safe ingredients upon those who bring their products within the jurisdiction of the Act. There is no prohibition against the use of untested or otherwise dubious ingredients in unstandardized foods. Should the unscrupulous or careless manufacturer elect to do so, if the government believes that an ingredient is unsafe, it is incumbent upon it to develop the necessary evidence to sustain its position in a court action. In the case of foods which are being considered for standardization under the provisions of section 401 of the Act, the mandate that foods so standardized shall promote honesty and fair dealing in the interest of consumers has provided the Secretary with an opportunity to inquire into the safety of the ingredients proposed for use in the product to which they are added. The authority of the Secretary to exclude from a standardized food an ingredient of questionable safety was challenged following the promulgation of the bread standards. After extensive hearings an order was issued excluding polyoxyethylene-type surface-active agents from the standardized bread products. The United States Court of Appeals for the Third Circuit in upholding the action stated in part:

"On the whole record the Administrator properly concluded that the safety of the questioned products had not been established although he was unable to conclude that they were deleterious." Thus, the Court has interpreted the standard-making provisions of the law as providing a safeguard against the use of an ingredient of undetermined safety, which the law does not provide in the case of unstandardized foods.

In 1950 it was brought out in testimony at hearings before the House Select Committee to Investigate the Use of Chemicals in Food Products, that as of approximately four years ago there were some seven hundred and four chemicals thought to be used in foods at that time, of which approximately 428 were "probably safe" as normally used. This prompted the then Commissioner, Mr. Crawford, to state at a meeting of Food and Drug officials.

"This leaves an interesting field for speculation as to work to get the facts about the presumed safety of some of the 428 and about the undetermined safety of the remaining 276." Undoubtedly since that time there have been some additions to both lists as well as a few deletions.

Most of you are familiar with the fact that about the middle of May 1953 pharmacological investigations carried out on behalf of the primary manufacturers of the flavoring agent, coumarin, demonstrated that this substance adversely affected animals when consumed in quantities comparable to that to be found in human diets. Despite the fact that no direct evidence had been developed that the use of coumarin in foods was injurious to man, it is
to the credit of the responsible producers of the product that they discontinued the sale of coumarin for food purposes.

This illustrates the need and desirability of stopping and taking a fresh look at old problems from time to time. New techniques and new scientific knowledge may justify a new course of action. To the extent that our facilities permit, we are taking another look at the evidence with respect to certain certifiable food colors, flavors, and other substances in the light of newer criteria of safety and recently developed pharmacological evidence. It would not be possible to discuss in a paper of this length specific products of the kind we have been considering in this phase nor, I may confess, would I be capable of doing so. In this part of my discussion I have been talking about ingredients which are not necessary in the production of the food and which can be avoided in good manufacturing practice.

Turning now to another type of food additive, which is of increasing interest and concern, the problem is relatively new. It is the outgrowth of the rapid development of knowledge in the fields of animal nutrition and veterinary medicine. The effects of medication and feeding practices of food-producing animals on our human food supply is a problem to which we are devoting considerable attention. The facts as developed to date do not justify alarm but do warrant a critical analysis of any new developments. Some control over this field has been exercised by the Food and Drug Administration under the new drug provisions of the law. In a statement of policy entitled "New Drugs Intended for Animal Use," manufacturers, packers, and distributors of veterinary preparations and animal feeds were placed on notice of our position in this matter. The notice reads in part as follows:

"A number of products have been developed to promote fattening, increase milk or egg production, or effect other physiological changes in farm animals. Many of these compounds contain as active ingredients substances the toxicity of which is known to be of a high order. For example, thiouracil, a very potent drug, has been proposed for use to promote fattening. When such substances are added to food they render the food adulterated under section 402 (a) of the Federal Food, Drug, and Cosmetic Act.

"The Federal Security Agency regards sections 402 (a) and 408 of the Act as clear enunciations of congressional intent to deny the channels of interstate commerce to food containing added poisonous or deleterious ingredients which are unnecessary in its production or which can be avoided by good manufacturing practice.

"Since these compounds are intended to affect the structure or function of the body of animals and have not been previously used for such purposes, they are regarded as new drugs, requiring the submission of adequate evidence of their safety, as required by section 505 of the Act, before being marketed in interstate commerce.

"In considering a new-drug application for a product intended to effect physiological changes in farm animals, the Federal Security Agency will regard the absence of satisfactory evidence showing that the meat or other food obtained from animals to which the drug is entirely free of any poisonous or deleterious ingredient resulting therefrom at the time of marketing as ground for refusal to make the application effective."

In carrying out this interpretation of the Act voluminous data intended to establish the safety of food produced from animals fed such proposed new products have been reviewed. Where the evidence has satisfactorily established the absence of toxic or deleterious ingredients in the food portion of the animals or in the food products produced by such animals, the applications have been made effective and the products permitted interstate distribution.

Without minimizing the economic importance of these developments in the production of animal foods it will be our purpose to continue to resolve questions of doubt in favor of the consuming public to the extent to which we are authorized by the law.

Earlier I referred to a recent amendment to the Federal law dealing with the establishment of tolerances for pesticidal residues on fresh fruits and vegetables. A bill entitled "An Act to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Residues of Pesticide Chemicals in or on Raw Agricultural Commodities" was introduced by Representative A. L. Miller of Nebraska. After passage without a dissenting vote by both branches of the Congress during its last session it was approved and enacted into law by the President on July 22, 1954. Commonly referred to as the Miller Pesticide Chemicals' Amendment this law makes two fundamental changes, both designed to simplify and expedite the establishment of safe tolerances for pesticide chemical residues on raw agricultural commodities. It assigns to the Secretary of Agriculture the functions of determining the agricultural usefulness of pesticide chemicals and probable residue levels resulting from their use. The responsibility for determining what residue levels may be safely tolerated without hazard to man is vested in the Secretary of Health, Education, and Welfare. In place of the formal and somewhat cumbersome procedure prescribed by the law prior to its amendment the new law emphasizes informal procedures. The amendment encourages the resolution of complex technical problems in a scientific atmosphere rather than in the give and take of a hard fought law suit. It places upon the proponents of a new economic poison greater responsibility for the development and presentation of basis facts about the article prior to its commercial distribution or to a consideration by the Secretary of the Department of a tolerance for residues resulting from use of the product. A further provision is made in the case of differences of opinion or uncertainties as to the proper action to follow for reference of the problem to an advisory committee. The law provides that the advisory committee shall be composed of experts qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from Land Grant Colleges. The right of judicial review in a formal proceeding is reserved the petitioner or other adversely affected party if the problem cannot be resolved through the informal procedures provided by the amendment.

Yesterday proposed regulations dealing with pesticidal residues were announced. The proposed regulations are in two parts. The first regulation proposes tolerances for 28 pesticides in common use based on scientific data developed at hearings held in 1950 under
section 406 of the Federal Food, Drug, and Cosmetic Act. The second regulation sets up operating procedures under the Miller Pesticide Chemical's Amendment. Obviously it would be premature to attempt any predictions as to how the new law will function in actual practice. During its legislative consideration it was supported by the pesticide manufacturers and by representatives of the food manufacturing industry, as well as by the Department of Health, Education, and Welfare and the Department of Agriculture. It undoubtedly reflects the hard-won experience gained by both the government and industry in proceedings under the former provisions of the law and certainly it reveals the earnest desires of the pesticide manufacturers, the food industry, the government, and the public as a whole for more effective laws to insure the safety of our food supply.

Before passing to the question of vitamin fortification of foods under the Federal law, I wish merely to refer to two other types of food additives which are of current importance and which present their own peculiar problems. The first is the increasing use of artificial nonnutritive sweeteners in foods. In our opinion a substantial number of these products are of dubious legality under the law and clarifying court decisions may be necessary to resolve their legal status. Some time ago the Food and Drug Administration requested the National Research Council to study the nutritional questions raised by this development as an aid to us in reappraising our present policies and regulations dealing with this field with a view to revision if the facts warrant. The second type of additive is that which results from the transfer to foods of certain components of food wrappers or other food containers. Some of these substances are added to the food wrap for antimycotic effect or other special purposes and which are intended to become a part of the food. In other instances the components of the wrapping material accidentally become a part of the food which raises the question of their suitability for food container use.

Turning now to the vitamin fortification of foods. When scientific developments made it possible to produce commercially at reasonable cost various vitamins in pure or concentrated form, food manufacturers were naturally quick to grasp the opportunity to add these substances to their food products. Undoubtedly, some were genuinely interested in improving the nutritional value of their products. Others saw in this new scientific development excellent advertising opportunities with little or no regard to whether the added nutritional factors would make any significant contribution to consumers. All of you are familiar, at least in a general way, with the development of the flour and bread enrichment program and the earlier pioneering effort to improve the nutritional value of a common food by fortification of common table salt with potassium iodide which was initiated in this country by the manufacturers upon the recommendation of the Michigan State Department of Health and the Michigan State Medical Society.

Today it would be very difficult to name a food which someone has not advocated be fortified. Many of these proposals have reminded Dr. E. M. Nelson, Chief of our Division of Nutrition, of a cartoon which he has had for many years. It depicts a meeting of the board of directors of an oil company with the chairman making this statement, "Our research department has succeeded in adding vitamin B1 to our gasoline, now it is trying to think of a reason for doing it." The Food and Drug Administration believes that the research department should develop the reasons for adding special nutritive ingredients to foods before attempting to find out how to do it.

Shortly after the effective date of the Federal Food, Drug, and Cosmetic Act of 1906, it became apparent that food fortification would become an important matter of consideration in establishing legal standards under the provisions of the law. It was important therefore that some basic policy in this field be developed by the Administration which would be in keeping with the fundamental purposes of the statute and scientific knowledge in the field of nutrition. After the standards for flour products were announced in 1941 a court review of the order establishing the definitions and standards for farina and enriched farina was obtained by one company. One of the issues raised was the authority of the Administrator to prohibit the marketing of wholesome, honestly labeled products through the standard-making provisions of the law. In one of the most important Supreme Court decisions affecting the enforcement of the Federal Food, Drug, and Cosmetic Act the government's position was sustained. While perhaps, many of you are familiar with this decision, it seems to me that portions of it are worth repeating at this time.

"Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drugs Act of 1906 but it was found that such a prohibition was inadequate to protect the consumer from economic adulteration . . . . The remedy chosen was not a requirement of informative labeling. Rather it was the purpose to authorize the Administrator to prescribe definitions and standards of identity 'under which the integrity of food products can be effectively maintained' . . . . The provisions for standards of identity thus reflect a recognition by Congress of the inability of consumers in some cases to determine solely on the basis of informative labeling the relative merits of a variety of products superficially resembling each other . . . . Taking into account the evidence of public demand for vitamin enriched foods, their increasing sale, their variable vitamin composition and dietary value and the general lack of consumer knowledge of such values, there was sufficient evidence of 'rational probative force' to support the Administrator's judgment that in the absence of appropriate standards of identity consumer confusion would ensue."

Thus, again, for other reasons, the standard-making provisions of the law permit a control over ingredients not available in the case of unstandardized products.

On the basis of the experience gained in the establishment of standards for flour and the support accorded the Department's position by this decision, a statement of policy with respect to the addition of nutritive ingredients to foods was issued in July of 1943. The criteria expressed in this statement remain today as the standards of judgment by which we appraise proposals to fortify foods. While somewhat lengthy I hope you will forgive me if, because of its importance and your apparent interest in the
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It is highly probable that a diet of unenriched foods so chosen as to contain the required quantities of the presently known needed vitamins and other factors would more nearly supply all needed factors, known and unknown, than a diet which is raised by enrichment to adequacy in the vitamins and minerals now known to be needed.

Even though adequate nutrition could be better assured through the choice of natural foods than through reliance on enrichment, unenriched foods of the kinds and in the quantities necessary for adequate nutrition are not now available to substantial parts of the population and are not likely to be available soon; nor are most consumers sufficiently educated on nutritional questions to enable them to make an intelligent choice of combinations of unenriched foods on the basis of nutritional values.

Because of the lack of adequate production, the number of foods high in certain nutrients and the lack of consumer knowledge of nutrition, appropriate enrichment of a few foods widely consumed by the population in general or by significant population groups will contribute substantially to the nutritional welfare of persons and to meeting their expectations of benefit. Enrichment of those foods which are not a substantial part of the dietary of any significant group tends to confuse and mislead consumers through giving rise to confusion of nutritional values and by creating an exaggerated impression of the benefits to be derived from the consumption of such foods.

If the customary process of manufacturing a staple food refines it so as to remove significant quantities of nutritive factors present in the natural product from which the food is made, and if the refined food is a suitable and efficient carrier of the factors so removed, some nutritionists advocate the restoration of such factors to the levels of the natural product as a desirable basis of enrichment. To the extent that restoration serves to correct deficiencies of such factors, it is consistent with the promotion of honesty and fair dealing that refined foods be enriched on a restoration basis. However, when the evidence shows that the restoration levels are too low to correct deficiencies, or that deficiencies exist in other factors for which the refined food is an efficient carrier, the promotion of honesty and fair dealing may require the inclusion of corrective quantities of nutritive factors in the enriched foods even though such factors are present in smaller quantities or wholly lacking in the natural product from which the food is made. Similar considerations may require the enrichment of unrefined foods.

Up to the present time standards for fortified foods have been established under the Federal law for the following products:

- Enriched bread and enriched rolls, enriched flour and enriched related products, enriched macaroni products, enriched noodle products, evaporated milk with a provision of the optional addition of vitamin D, oleomargarine with a provision for the optional addition of vitamin A, and various enriched corn products.

There are, of course, many unstandardized products on the market to which various vitamins and minerals have been added. That many of these products fail to measure up to the philosophy in the Department’s policy announcement on this question is apparent.

In closing may I again express my appreciation for this opportunity to meet with you and to express on behalf of the Food and Drug Administration our good wishes for the continuing success of your association and to its individual members.

REPORT OF THE COMMITTEE ON EDUCATION AND PROFESSIONAL DEVELOPMENT — 1954

The Committee on Education and Professional Development during the current year has directed its efforts and attention to two specific interests. The first of these involved a proposal to establish scholarships at the academic level for students choosing the field of public health and sanitation as a college major. The second project undertaken concerned the drawing of a “model law” which might be used by state affiliates of the International as an act appropriate to recommend for passage by state legislative bodies. The model law in question establishes procedures for the legal registration of professional sanitarians.

In proposing the first of these two projects, namely a plan for academic scholarships, your committee was motivated by a number of pertinent facts, among which were the following:

a. The education and training of the sanitarian is fundamental to his professional development. If the sanitarian is to attain professional status there must be established a base from which to operate and this base must be closely correlated with his education and training. A scholarship plan is one tangible means of demonstrating the interest of this Association in the specialized and technical training of the sanitarian.

b. The number of persons electing public health training at the undergraduate level at institutions...